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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,332	03/14/2001	Keith P. Johnston	61112	3850

109 7590 12/30/2002

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,332

Applicant(s)

JOHNSTON ET AL.

Examiner

Amy E Pulliam

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment A, received by the Office October 1, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,985,248 to Gordon. Applicant is claiming a method for preparing particles of a poorly water soluble drug by dissolving the drug in an organic solvent, spraying the mixture into an aqueous solution, and evaporating the organic solvent.

Gordon teaches a method for preparing dry powders having hydrophobic and hydrophilic components by combining solutions or suspensions of the components and spray drying them simultaneously in a spray drier. More specifically, Gordon teaches dissolving a hydrophilic excipient in an organic solvent or cosolvent system, dissolving a hydrophobic drug in the same organic solvent or cosolvent system to produce an organic solution, and spray drying the solution to form particles comprising a mixture of the hydrophilic and hydrophobic components (claim 1). Furthermore, Gordon teaches that the process produces droplets of a liquid medium which are dried in a drying operation, which results in the formation of discrete particles (column 7,

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lines 1-10). Additionally, Gordon teaches the inclusion of excipients, such as povidone (column 5, lines 61-64). Furthermore, Gordon teaches the process will result in ultrafine particles, such as those with a size of less than 10 microns (column 6, line 4). Gordon further teaches that the particles are dispersible, if necessary for administration (column 6, line 58). Gordon also discusses the composition which results from his claimed method.

Applicant has amended the claims to include “wherein the drug/ organic mixture is sprayed at or below the liquid level of the aqueous solution.” The examiner asks applicant to discuss the criticality of such a limitation. It is unclear to the examiner what this limitation does to render unexpected results to the process. Furthermore, it is not apparent that this limitation changes the resulting product in any way. It is recommended that applicant provide evidence discussing and demonstrating the criticality of this new limitation.

It is the position of the examiner that one of ordinary skill in the art would have looked to the teachings of Gordon for a method of preparing dry powders. Applicant has provided no scientific evidence that the teachings of Gordon are patentably distinct from the teachings of applicant. It is requested that applicant provide more discussion of any significant differences between the teachings of Gordon and applicant.

For the above reasons, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant’s arguments have been fully considered but are not found to be persuasive. The limitation requiring the mixture to be sprayed at or below liquid level of the aqueous solution is discussed in the above rejection. Additionally, applicant argues that Gordon does not

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teach or suggest rapidly evaporating the organic solvent in the presence of the aqueous solution. The examiner does not find this argument persuasive. Applicant himself admits that how rapidly the organic solvent is evaporated will depend upon the temperature at which the evaporation takes place. The examiner points out that the instant claims contain to specific temperature ranges. Therefore, the use of the word "rapidly" is completely relative, and depends upon the specific temperature employed. Without specific temperatures and specific time limits, there is no basis for which to judge the word "rapidly", and therefore, it is interpreted broadly. As a result, it is the position of the examiner that Gordon's teaching can fall within a broad interpretation of the claim language. For these reasons, the above rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
December 23, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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